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# HOUSE BILL No. 1293

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## DIGEST OF INTRODUCED BILL

**Citations Affected:** IC 16-18-2; IC 16-42.5.

**Synopsis:** Prescription drug discounts. Establishes the Rx program to provide discounted prescription drug prices to uninsured persons, underinsured persons, and Medicare recipients. Allows a drug manufacturer or labeler that sells prescription drugs to voluntarily enter into a rebate agreement with the state department of health that requires rebate payments to be made to the state for the Rx program. Authorizes the state department to negotiate the amount of the rebate and audit a manufacturer or labeler to assure compliance. Requires a retail pharmacy to sell the drugs covered by the Rx program to participants in the program at the discounted price. Establishes: (1) a formula for the state to use in calculating discount prices for drugs covered by the rebate agreement; (2) a procedure for resolving rebate amount discrepancies; and (3) the Rx dedicated fund, consisting of revenue from manufacturers and labelers who pay rebates and appropriations to the fund.

**Effective:** July 1, 2002.

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### Kersey, Liggett

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January 14, 2002, read first time and referred to Committee on Ways and Means.

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Introduced

Second Regular Session 112th General Assembly (2002)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2001 General Assembly.

## HOUSE BILL No. 1293

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A BILL FOR AN ACT to amend the Indiana Code concerning health.

*Be it enacted by the General Assembly of the State of Indiana:*

1       SECTION 1. IC 16-18-2-32.5 IS ADDED TO THE INDIANA  
2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
3 [EFFECTIVE JULY 1, 2002]: **Sec. 32.5. "Average wholesale price",**  
4 **for purposes of IC 16-42.5, has the meaning set forth in**  
5 **IC 16-42.5-1-2.**

6       SECTION 2. IC 16-18-2-197.5 IS ADDED TO THE INDIANA  
7 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
8 [EFFECTIVE JULY 1, 2002]: **Sec. 197.5. "Labeler", for purposes of**  
9 **IC 16-42.5, has the meaning set forth in IC 16-42.5-1-3.**

10       SECTION 3. IC 16-18-2-216 IS AMENDED TO READ AS  
11 FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 216. (a)  
12 "Manufacturer", for purposes of IC 16-42-19, ~~and~~ IC 16-42-21, **and**  
13 **IC 16-42.5**, means a person who, by compounding, cultivating,  
14 harvesting, mixing, or other process, produces or prepares legend  
15 drugs. The term includes a person who:

16               (1) prepares legend drugs in dosage forms by mixing,  
17               compounding, encapsulating, entableting, or other process; or

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(2) packages or repackages legend drugs.

(b) The term does not include pharmacists or practitioners (as defined in section 288(a) and 288(c) of this chapter) in the practice of their profession.

SECTION 4. IC 16-18-2-318.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 318.5. "Retail pharmacy", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-4.**

SECTION 5. IC 16-18-2-320.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 320.8. "Rx program", for purposes of IC 16-42.5, refers to the Rx program established by IC 16-42.5-2-1.**

SECTION 6. IC 16-18-2-374 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 374. (a) "Wholesaler", for purposes of IC 16-42-11, has the meaning set forth in IC 16-42-11-3.**

**(b) "Wholesaler", for purposes of IC 16-42-19, and IC 16-42-21, and IC 16-42.5, has the meaning set forth in IC 16-42-19-10.**

**(c) "Wholesaler", for purposes of IC 16-41-32, has the meaning set forth in IC 16-41-32-13.**

SECTION 7. IC 16-42.5 IS ADDED TO THE INDIANA CODE AS A NEW ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]:

**ARTICLE 42.5. FAIR PRICING FOR PRESCRIPTION DRUGS**

**Chapter 1. Definitions**

**Sec. 1. The definitions in this chapter apply throughout this article.**

**Sec. 2. "Average wholesale price" means the wholesale price assigned by a drug manufacturer to a specific commodity that is listed in a nationally recognized drug pricing file.**

**Sec. 3. "Labeler" means a person or an entity that:**

**(1) receives prescription drugs from a manufacturer or wholesaler;**

**(2) repackages those drugs for later retail sale; and**

**(3) has a labeler code from the federal Food and Drug Administration under 21 CFR 207.20.**

**Sec. 4. "Retail pharmacy" means a retail pharmacy or another business that is licensed to dispense prescription drugs in Indiana and either:**

**(1) participates in the state Medicaid program; or**



(2) voluntarily agrees to participate in the Rx program.

## **Chapter 2. General Provisions**

**Sec. 1. The Rx program is established to provide discounted prescription drug prices to the following Indiana residents:**

(1) Uninsured persons.

(2) Underinsured persons.

(3) Medicare recipients.

**Sec. 2. (a) Subject to subsection (b), an Indiana resident is eligible to participate in the Rx program if the resident meets any of the following criteria:**

(1) The resident is eligible for Medicare.

(2) The resident has a net family income of not more than four hundred percent (400%) of the federal poverty level.

(3) The resident has a single wage earned income of not more than three hundred percent (300%) of the federal poverty level.

**(b) An Indiana resident is ineligible for the Rx program if the individual:**

(1) is eligible for Medicaid; or

(2) has prescription drug coverage under any health insurance plan or public assistance program in which the prescription drug coverage is equal to or greater than the Rx program benefits.

**(c) The state department shall establish simplified procedures for determining eligibility and issuing Rx program enrollment cards.**

**(d) The state department shall undertake outreach efforts to build public awareness of the Rx program and maximize enrollment.**

**(e) The state department may adjust the requirements and terms of the Rx program to accommodate any new federally funded prescription drug program.**

**Sec. 3. The state department shall submit a report on the enrollment and financial status of the Rx program to the legislative council before January 1 of each year.**

**Sec. 4. The department may adopt rules under IC 4-22-2 to implement this article.**

**Sec. 5. The state department may do the following in implementing the Rx program:**

(1) Coordinate with other governmental programs.

(2) Take actions to enhance efficiency.

(3) Reduce the cost of prescription drugs.

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(4) Maximize the benefits of the Rx program and other governmental programs, including providing the benefits of the Rx program to other state program beneficiaries.

Sec. 6. The state department shall apply for any waiver of federal law, rule, or regulation necessary to implement this article.

**Chapter 3. Requirements of Drug Manufacturers and Labelers**

Sec. 1. (a) A drug manufacturer or labeler that sells prescription drugs in Indiana may voluntarily elect to provide prescription drug discounts by entering into a Rx rebate program established under this article with the state department.

(b) The rebate agreement voluntarily entered into under this chapter must require the manufacturer or labeler to make rebate payments to the state each calendar quarter according to a schedule established by the state department.

Sec. 2. (a) The state department shall negotiate the amount of the rebate voluntarily provided by a manufacturer or labeler in accordance with this chapter.

(b) When negotiating the amount of the rebate, the state department must consider the following:

(1) The rebate calculated under the federal Medicaid Rebate Program under 42 U.S.C. 1396r-8.

(2) The average wholesale price of prescription drugs.

(3) Any other information on prescription drug prices and price discounts.

(c) The state department shall use its best efforts to obtain a rebate amount that is at least equal to the amount of any discount, rebate, or price reduction for prescription drugs that is provided to the federal government.

Sec. 3. (a) The names of manufacturers and labelers that enter into rebate agreements established under IC 16-42.5-2-1 are public information, and the state department shall release this information to the public.

(b) The state department shall distribute to:

(1) physicians;

(2) pharmacists; and

(3) other health professionals;

information about the cost of prescription drugs produced by manufacturers and labelers that enter into rebate agreements established under IC 16-42.5-2-1 and the cost of prescription drugs of manufacturers and labelers that have not entered into a rebate agreement.

Sec. 4. (a) For each manufacturer or labeler of prescription

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1 drugs that does not enter into a voluntary rebate agreement with  
 2 the state department, the state department shall review the issue of  
 3 the manner by which physicians disperse prescription drugs of the  
 4 manufacturer or labeler under the prescription drug component  
 5 of the state Medicaid program.

6 (b) The state department shall adopt rules under IC 4-22-2 to  
 7 carry out this chapter.

#### 8 Chapter 4. Calculation of Discount Price

9 Sec. 1. The state department shall establish discounted prices at  
 10 which a retail pharmacy must offer prescription drugs covered by  
 11 a rebate agreement and shall promote the use of effective and  
 12 reduced cost drugs.

13 Sec. 2. (a) The state department shall use the following formula  
 14 to compute the discount prices described in section 1 of this  
 15 chapter:

16 STEP ONE: Determine the average wholesale price.

17 STEP TWO: Subtract six percent (6%) of the wholesale price  
 18 from the wholesale price.

19 STEP THREE: Add a designated dispensing fee that is at least  
 20 the amount of the dispensing fee provided under the state  
 21 Medicaid program.

22 (b) The state department shall use the following formula to  
 23 compute the price at which a retail pharmacy must offer a  
 24 prescription drug:

25 STEP ONE: Use the subsection (a) STEP THREE amount.

26 STEP TWO: Subtract the rebate paid by the state to a retail  
 27 pharmacy.

#### 28 Chapter 5. Sale of Prescription Drugs at Discounted Prices

29 Sec. 1. (a) A retail pharmacy may not charge more than the  
 30 amount computed by the state department under IC 16-42.5-4-2(b)  
 31 for drugs covered by the Rx program and sold to Rx program  
 32 participants.

33 (b) The state department shall specify the discounted price  
 34 levels.

35 (c) In determining the discounted price levels, the state  
 36 department may consider an average of all rebates weighted by  
 37 sales of drugs subject to these rebates over the most recent twelve  
 38 (12) month period for which the information is available.

#### 39 Chapter 6. Operation of the Rx Program

40 Sec. 1. (a) The Indiana board of pharmacy established by  
 41 IC 25-26-13-3 shall adopt rules requiring disclosure by retail  
 42 pharmacies to Rx program participants of the amount of savings

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provided by the Rx program.

(b) The rules adopted under subsection (a) must consider and protect information that is proprietary in nature.

Sec. 2. (a) A retail pharmacy shall submit claims to the state department to enable the state department to verify the amounts charged to Rx program participants.

(b) The state department may not impose transaction charges on retail pharmacies that submit claims or receive payments under the Rx program.

Sec. 3. (a) On a weekly or biweekly basis, the state department shall:

(1) reimburse a retail pharmacy for discounted prices provided to Rx program participants; and

(2) subject to IC 16-42.5-4-2(a), pay a retail pharmacy a dispensing fee set by the state department for each prescription dispensed by the retail pharmacy to Rx program participants.

(b) Unless a different amount is set by the state department under subsection (a) and subject to IC 16-42.5-4-2(a), the professional fee is three dollars (\$3) per prescription.

Sec. 4. (a) The state department shall collect from each retail pharmacy utilization data necessary to calculate the amount of the rebate from a manufacturer or labeler, including statistics concerning the sale of prescription drugs to Rx program participants and other customers.

(b) The state department shall protect information that is confidential or proprietary in nature.

#### Chapter 7. Discrepancies in Rebate Amounts

Sec. 1. Discrepancies in rebate amounts must be resolved using the process established in this chapter.

Sec. 2. (a) If the manufacturer or labeler rebates less than the amount claimed by a retail pharmacy, resulting in a discrepancy that favors the manufacturer or labeler, the state department, at the state department's expense, may hire a mutually agreed upon independent auditor to conduct an audit to verify the accuracy of the data supplied by the manufacturer or labeler concerning the amount of the rebate.

(b) If a discrepancy exists following an audit by the independent auditor hired by the state department, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the state department for any additional rebate amount due.

Sec. 3. (a) If the manufacturer or labeler rebates more than the

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amount claimed by a retail pharmacy, resulting in a discrepancy against the interest of the manufacturer or labeler, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed upon independent auditor to verify the accuracy of the data supplied to the state department regarding the manufacturer's or labeler's rebate amount.

(b) If a discrepancy exists following an audit by the independent auditor hired by the manufacturer or labeler, the state department shall justify the reason for the discrepancy or refund to the manufacturer any excess rebate payment made by the manufacturer or labeler.

Sec. 4. Following the procedures established in sections 2 and 3 of this chapter, either the state department or the manufacturer or labeler may request a hearing under IC 4-21.5 if there is a dispute under this chapter.

#### Chapter 8. Rx Dedicated Fund

Sec. 1. As used in this chapter, "fund" refers to the Rx dedicated fund established by section 2 of this chapter.

Sec. 2. (a) The Rx dedicated fund is established. The fund consists of:

- (1) revenue from manufacturers and labelers who pay rebates; and
- (2) appropriations or allocations to the fund.

(b) The purpose of the fund is to reimburse retail pharmacies for discounted prices provided by the pharmacies to Rx program participants. The fund shall be administered by the state department.

(c) The expenses of administering the fund, including the following, shall be paid from money in the fund:

- (1) Contracted services.
- (2) Computer costs.
- (3) Retail pharmacy dispensing fees.
- (4) Other reasonable Rx program costs.

(d) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested. Interest that accrues from these investments shall be deposited in the fund.

(e) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

#### Chapter 9. Terms of Rebate Agreement

Sec. 1. (a) A rebate agreement entered into under IC 16-42.5-3-1 must include a verification by the manufacturer or labeler that the

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price negotiated in the rebate agreement complies with this article.

(b) The state department may perform an audit of any manufacturer or labeler who has entered into a rebate agreement to determine whether the manufacturer or labeler complied with subsection (a). The state department may contract with an independent individual or organization to carry out the state department's duties under this subsection. A manufacturer or labeler shall provide information that the state department may reasonably require to enable it to determine whether the manufacturer or labeler is in compliance with this chapter.

(c) If the state department or its agent determines that a manufacturer or labeler has not complied with subsection (a), the state department shall require the manufacturer or labeler to do the following:

(1) Refund to the state department the difference between the price offered to the state by the rebate agreement and the lowest price offered by the manufacturer or labeler as determined by the state department's negotiating formula under IC 16-42.5-3 and IC 16-42.5-4.

(2) Promptly pay the costs of the audit.

(d) The state may hire counsel to collect any amount, including attorney's fees and the cost of collection, under subsection (c) that is not promptly paid.

(e) The state department shall deposit any money collected under subsection (c) into the Rx dedicated fund.

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